



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF
ENFORCEMENT AND
COMPLIANCE ASSURANCE

Rebecca L. Stankiewicz Gabel, PhD
Biotechnology Regulatory Services
U.S. Department of Agriculture
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Unit 147
Riverdale, MD 20737-1236

Dear Dr. Gabel:

In accordance with our responsibilities under Section 309 of the Clean Air Act and the National Environmental Policy Act (NEPA), the U.S. Environmental Protection Agency (EPA) has reviewed the U.S. Department of Agriculture (USDA), Animal Plant Health Inspection Service (APHIS) draft environmental impact statement (EIS) for *Glyphosate-Tolerant H7-1 Sugar Beets: Request for Nonregulated Status*.

APHIS prepared this draft EIS in response to a petition from Monsanto/KWS SAAT AG seeking a determination of non-regulated status of its glyphosate-tolerant H7-1 sugar beets. This sugar beet cultivar is genetically engineered (GE) to be resistant to the herbicide glyphosate and is marketed as a tool for managing weeds in sugar beet production.

The draft EIS considered three alternatives based on their ability to fulfill APHIS regulatory requirements and their ability to be implemented by APHIS: Alternative 1, No Action, denies the petition seeking a determination of non-regulated status of H7-1 sugar beets; Alternative 2, Full Deregulation of H7-1, grants a determination of non-regulated status; and Alternative 3, Partial Deregulation, utilizes various levels of regulation to allow large-scale cultivation of H7-1 sugar beets. The draft EIS identified Alternative 2, (Full Deregulation of H7-1) as APHIS' preferred alternative.

We have not identified any potential impacts requiring substantive changes to the preferred alternative, and have assigned the draft EIS for *Glyphosate-tolerant H7-1 Sugar Beets: Request for Nonregulated Status* a rating of LO (Lack of Objections). See enclosure "Summary of EPA Rating System" for more detailed information on the rating system). We are also enclosing technical comments that provide recommendations for further clarification and additional discussion in the final EIS.

We appreciate the opportunity to review this draft programmatic EIS. If you should have any questions, please contact me at (202) 564-5400 or Arthur Totten, the staff contact for this project at (202) 564-7164.

Sincerely,



Susan E. Bromm
Director
Office of Federal Activities

Enclosures

Summary of EPA Rating System: Definitions and Follow-up Action

Environmental Impact of the Action

LO--Lack of Objections

The EPA review has not identified any potential environmental impacts requiring substantive changes to the proposal. The review may have disclosed opportunities for application of mitigation measures that could be accomplished with no more than minor changes to the proposal.

EC--Environmental Concerns

The EPA review has identified environmental impacts that should be avoided in order to fully protect the environment. Corrective measures may require changes to the preferred alternative or application of mitigation measures that can reduce the environmental impact. EPA would like to work with the lead agency to reduce these impacts.

EO--Environmental Objections

The EPA review has identified significant environmental impacts that must be avoided in order to provide adequate protection for the environment. Corrective measures may require substantial changes to the preferred alternative or consideration of some other project alternative (including the no action alternative or a new alternative). EPA intends to work with the lead agency to reduce these impacts.

EU--Environmentally Unsatisfactory

The EPA review has identified adverse environmental impacts that are of sufficient magnitude that they are unsatisfactory from the standpoint of public health or welfare or environmental quality. EPA intends to work with the lead agency to reduce these impacts. If the potentially unsatisfactory impacts are not corrected at the final EIS stage, this proposal will be recommended for referral to the CEQ.

Adequacy of the Impact Statement

Category 1--Adequate

EPA believes the draft EIS adequately sets forth the environmental impact(s) of the preferred alternative and those of the alternatives reasonably available to the project or action. No further analysis or data collection is necessary, but the reviewer may suggest the addition of clarifying language or information.

Category 2--Insufficient Information

The draft EIS does not contain sufficient information for EPA to fully assess environmental impacts that should be avoided in order to fully protect the environment, or the EPA reviewer has identified new reasonably available alternatives that are within the spectrum of alternatives analyzed in the draft EIS, which could reduce the environmental impacts of the action. The identified additional information, data, analyses, or discussion should be included in the final EIS.

Category 3--Inadequate

EPA does not believe that the draft EIS adequately assesses potentially significant environmental impacts of the action, or the EPA reviewer has identified new, reasonably available alternatives that are outside of the spectrum of alternatives analyzed in the draft EIS, which should be analyzed in order to reduce the potentially significant environmental impacts. EPA believes that the identified additional information, data, analyses, or discussions are of such a magnitude that they should have full public review at a draft stage. EPA does not believe that the draft EIS is adequate for the purposes of the NEPA and/or Section 309 review, and thus should be formally revised and made available for public comment in a supplemental or revised draft EIS. On the basis of the potential significant impacts involved, this proposal could be a candidate for referral to the CEQ.

U.S. Environmental Protection Agency
Detailed Comments on Draft EIS for
Glyphosate-Tolerant H7-1 Sugar Beets: Request for Nonregulated Status

Detailed Comments:

- 1.) **Page 241: last para**, the statement “...*(1) use the desired herbicide until resistance occurs and then change to an alternative*” as a resistance management option should be changed or removed. This is as an example of not following a resistance management strategy and is contrary to current efforts made in the education of herbicide applicators to proactively manage resistance.
- 2.) **Page 130: last para, under Hand Hoeing**, the characterization of weed thresholds in the EIS should be corrected and/or clarified; for example, not all weed species have an established threshold for control.
- 3.) **Page 227: third para**, is the statement “... *On the other hand, some chemical’s TGAI could be more toxic than the TEP, owing to the lower concentration of the a.i. in the TEP than in the TGAI....*” based on total mass/volume, and not when the TEP is adjusted for % a.i. for comparison to the TGAI value?
- 4.) **Page 547: last para**, EC50 should be replaced with EC05 in the statement “... *If a NOEL value was not determined, the EC50 can be used instead....*”
- 5.) **Page ix: 1st para, 1st sentence** states, “*There could be a risk of sub lethal or chronic effects on mammals...*” According to the 2005 Reregistration Eligibility Decision (RED), pyrazon has very minimal effects on mammals.
- 6.) **Section III, F, 1, b. Pesticides.**

Page 355: 1st bullet, states, “The toxicity of the pesticides and its break-down products;” We suggest rewording to read: “The toxicity of the pesticides and its major break-down products;”
- 7.) **Section IV, F, 1, b. Pesticides.**

Page 617: 2nd para, the title for the description “*Chronic Oral Reference Dose (RfD)*” should be reworded to: “Oral Reference Dose”. Also, in this paragraph, the sentence stating, “The RfD is a value established by EPA that is based on toxicity studies in laboratory animals and adjusted...” should be reworded to: “The RfD is a value chosen by EPA, from relevant toxicity data, and adjusted...”

Page 617: 1st bullet, under the description for dietary risk assessment for food, the statement, “The risk is expressed as a percentage of a maximum acceptable dose (i.e., the dose which will result in no unreasonable adverse health effects) (U.S. EPA 2004).” should be reworded to: “The risk is expressed as a percentage of a maximum acceptable dose (i.e., the dose which is not expected to result in unreasonable adverse health effects) (U.S. EPA 2004).” Also, in this paragraph, the fourth and last sentences, where “aPAD” and/or “cPAD” are referenced, should be replaced with “aRfD” and “cRfD”.

Page 617: 1st bullet, 4th sentence, states, “*Dietary risk is characterized...for the Food Quality Protection Act (FQPA) Safety Factor*” should be reworded to state, “Dietary risk is characterized...for the Food Quality Protection Act (FQPA) Safety Factors and is therefore considered the PAD.”

Page 617: 1st bullet, 5th sentence, states, “*A risk estimate that is less than 100%...*” should be reworded to state, “Estimated dietary exposure less than 100% of the PAD is not expected to be of concern to the Agency.”

Page 623: 1st bullet, 2nd sentence, states, “*In general, the lower the RfD value, the higher the toxicity (or the greater the uncertainty); alternatively, the lower the RfD, the higher the risk given the same dose or exposure.*” should be reworded to state, “In general, if uncertainties of the database are equal, the lower the RfD the greater the potency of the toxicity: by extension, the lower the RfD, the higher the risk given the same dose or exposure.”

Page 623: 2nd bullet, 1st sentence, states “*...as percent of the chronic public adjusted dose...*” should be reworded to state, “*...as percent of the chronic population adjusted dose...*” Overall this paragraph does not provide clarity on the aggregate component (risk and exposure).

Page 623: 3rd para, notes that application method is not considered in the various risk matrices listed on the previous page. EPA notes that application method is, indirectly, incorporated into dietary risk assessments. EPA cannot comment on the other risk matrices.

Page 624: 2nd para, 1st sentence, we suggest you cite a source that supports the position that data Alternative 2 is not expected to lead to an increase in the exposure.

8.) **Section IV, F, 2, b. Pesticides.**

Page 627: last para, 3rd sentence, states, "*Signal words are based on acute toxicity testing of the concentrated product by oral, inhalation, dermal, skin sensitization, and eye exposures.*" should be reworded to state: "Signal words are based on acute toxicity testing of the concentrated product by oral, inhalation, dermal, skin sensitization, and eye exposures (discussed briefly below)."

- 9.) **Page 365: 3rd para, 4th sentence**, reads, "...it is not a dermal sensitizer", should be corrected to say that it is a dermal sensitizer. (According to EPA's risk assessment.)
- 10.) **Page 381: 4th para, 1st sentence**, states, the tolerance as 0.5 ppm for triflurosulfuron-methyl; should be corrected this to show 0.05 ppm instead.
- 11.) **Page 401:** The statement that MOE values posed risks of concern should be removed. MOEs are well above 100 and therefore there are no risks of concern.
- 12.) **Page 622:** The comments below refer to the highlighted entries in the column entitled "*Chronic dietary risk assessment for food*" in Table 4-26, (a copy of Table 4-26 is also shown below).

Desmedipham:

ND The risk assessment that was cited states "... *The most highly exposed population subgroup in the chronic dietary exposure analysis is children 3-5 years of age; 0.000083 mg/kg/day or < 1% of the cPAD (D301554, S. Kinard, 6/1/2004).*" Therefore, this value can be <1/<1.

Pyrazon:

<0.1/<0.1 These values are for food only. For food and drinking water, the values are 5.8% (Lifeline) and 7.8% (DEEM) for US population and 21% (Lifeline) and 25% (DEEM) for all infants <1 year (subgroup with highest exposure).

Quizalofop-p-ethyl:

/29 The US population utilized 11% of the cPAD; therefore, this value should be 11/29.

Trifluralin:

(No value assigned) The RED cited included the following information: The Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population was 3% and highest exposed subgroup, non-nursing infants, was 10%. The RED also included anticipated residue contributions for the US population (1%) and non-nursing infants (2%). The value 3/10 can be used here.

Table 4-26. Selected Hazard Metrics for Public Exposures ¹						
Herbicide	APHIS Relative Risk Score	WIN-PST Exposure Adjusted Toxicity Category	Consumer Environmental Impact Quotient (EIQ)	Chronic Oral Reference Dose (RfD)	Chronic dietary risk assessment for food ²	Aggregate Risk: Food, Water, Residential
Clethodim	12	Low	8	0.01	27/73	<LOC
Clopyralid	0.5	Very Low	8	0.15	9/23	<LOC
Cycloate	192	Intermediate	7	0.005	2.4/5.5	<LOC
Desmedipham	11	Very Low	2.55	0.04	ND	<LOC
EPTC	59	Very Low	4	0.025	9.6/17.4	<LOC
Ethofumesate	3	Very Low	6	0.3	<1/<1	<LOC
Glyphosate	1	Very Low	3	1.75	2/7	<LOC
Phenmedipham	3	Very Low	4.55	0.24	<1/<1	<LOC
Pyrazon	10	Very Low	7	0.18	<0.1/<0.1	<LOC
Quizalofop-p-ethyl	5	Low	3.33	0.009	/29	<LOC
Sethoxydim	2	Very Low	4.55	0.14	2.7/7.5	<LOC
Trifluralin	8	Intermediate	5.5	0.024		<LOC
Triflurosulfuron-methyl	0.8	Intermediate	-	0.024	<1/<1	<LOC
¹ See the introduction to section IV.F.2.b for the derivation of each of these metrics ² Percent of RfD or cPAD. The first value is for the general public; the second is for the highest exposed subgroup						
² Abbreviations: WIN-PST = Windows pesticide screening tool, LOC= Level of concern; ND –not determined						

- 13.) **Page 629: last para, last sentence,** Acute dermal LD50 for quizalofop-p-ethyl is shown as 2,000 mg/kg. This should be corrected to $\geq 5,000$ mg/kg as per the risk assessment.
- 14.) **Page 476: Table 4-7,** indicates that “AMPA is a microbial degrade of glyphosate which appears to be less toxic than glyphosate. EPA has not assessed AMPA in the past.” Environmental effects of the degradation products of herbicides that are compared to glyphosate within this table are generally known. For this table to provide useful comparison, APHIS should strive to present any recent findings on environmental fate and effects of AMPA in the final EIS. EPA has considered AMPA in past ecological risk assessments and indicated that the toxicity of AMPA is less than that of glyphosate through acute ecotoxicity studies on birds, fish and freshwater invertebrates. EPA therefore decided not to specifically assess AMPA separately from glyphosate as it is not considered a residue of concern. The statement that “EPA has not assessed AMPA in the past” is therefore not accurate and should be changed. Any new information APHIS may have regarding the potential environmental effects of AMPA should be noted as data are available.